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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,305	10/27/2004	Lionel Breton	112701-434	6006

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No. 10/505,305	Applicant(s) BRETON ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 25-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The amendment filed 6/27/07 is acknowledged. Claims 1-10 and 25-30 are being examined to the extent that they are directed to a bacterial culture only.

Claims 1-10 and 25-30 are withdrawn from consideration to the extent that they pertain to supernatants.

Claims 11-24 are withdrawn from consideration.

The rejection under 35 U.S.C 112, first paragraph regarding deposit is withdrawn in view of applicant's averments..

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the it is unclear whether the percentage by weight now recited pertains to each of the at least one probiotic lactic acid bacterium and at least one the carotenoid or to both together.

Also, the phrase "at least one carotenoid or derivative" is not particularly defined in the specification. It is noted that at page 15, paragraph 5 applicant provides some examples of carotenoids and points out some sources of such carotenoids. However, it is not clear which compounds are encompassed "carotenoid derivatives" in this context.

To clarify the invention, it is recommended that claims 1 and 4 be amended to recite "*Lactobacillus*" and "*Bifidobacterium*", which are the art accepted designations for the genera involved.

Claim 4 is confusing in lacking antecedent basis in claim 3, in that there are several *Lactobacillus* strains respectively *Bifidobacterium* strains belonging to various species and it cannot readily ascertained which of the deposited strains belongs to which species as written.. The correlation is unclear and should be specifically designated, for example, by inserting the appropriate species designation before the deposit number.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over of claim 9 of copending, currently commonly owned Application No. 10/505,285, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application is completely encompassed by the scope of the claims in the '305 application.

Instant claims are drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and carotenoid or derivatives thereof. Claim 9 of the '305 application is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid or derivative thereof and a yeast. Because claim 1 of the instant application uses open-claim language ("comprising"), this claim is fully encompassed by compositions comprising the two components of the '285 claim plus any other additional component. The generic nature of claim 9, which does not place any restrictions on the type or number of probiotic bacteria or carotenoids, or the physical form of the food composition, encompasses the specific claims of the instant application (2-10, 25-30).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 22-32 of copending, currently commonly owned Application No. 10/504,906, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application completely encompasses the scope of the claims in the '906 application.

The instant claims are drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and carotenoid or derivatives thereof. Claim 1 of the '906 application is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one yeast. The instant claims fully encompass claims to compositions comprising the probiotic '906 claim plus any other additional component such as a carotenoid producing yeast or a pharmaceutical product containing yeast..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending, Application No. 11/159198, which shares at least one inventor with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending applications are directed to the use of probiotic bacteria in cosmetic compositions which include the same strains, such as *L. johnsonii* CNCM I-1125, *L. paracasei* CNCM I-1126 and *Bifidobacterium longum* CNCM I-2170. The cosmetic compositions of the copending application would be expected to be photoprotective at least to some extent.

Therefore, the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The terminal disclaimer presented is acknowledged. However, it has not yet been reviewed .

Claims 1-10 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely *et al.* (EP 1020123) taken with Shields, Jr. *et al.* (U.S. Patent 6,156,355), Runge *et al.* (U.S. Patent No. 7,037,708), by Berggren *et al.* (WO/00/79072) and Brassart *et al.* U.S. Patent No. 5,603,930) and further taken with Reddy (U.S. Patent No. 4,806,368)

The claims are directed to an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier and including yeast extract.

As discussed *supra*, the cited references disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid or a derivative thereof, included in an ingestible carrier.

The references differs from the claimed invention in that the specific strains of claim 4 are not disclosed and in the provision of milk products, milk based fermented products such as yogurt.. However, Brassart *et al.* adequately demonstrates that at least strains CNCM I-1225 and CNCM I-1226 are old and well known in the art as probiotics. In addition the reference demonstrates that the composition is provided as a yogurt a milk-based fermented product. See, e.g., col. 3, lines 55-60.

With regard to the pharmaceutical carrier, it is noted that the product of Berggren is provided at least in table form. In addition, yogurt containing strain CNCM I-1225 comprises a pharmaceutical carrier.

Regarding the presence of yeast extract, it is noted that Reddy adequately demonstrates that *Lactobacillus* and *Bifidobacterium* compositions containing yeast extract are old and well known in the art. See, e.g., Col. 3, Table. The reference discloses the benefits of the yeast extracts components to the viability of the bacteria, for example as a source of B vitamins.

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The concentrations discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of concentrations for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of probiotic strains CNCM I-1225 and CNCM I-1226 as suggested by the teachings of Brassart *et al.* for the expected benefit of providing a healthful composition comprising a probiotic strain known to have favorable effects against disease and carotenoids such as β -carotene known to have at least antioxidants effects.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's preamble directed to the photoprotection of the skin is noted. It is noted that the Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.*, Berggren *et al.* are all directed to compositions comprising lactic acid probiotics and carotenoid or carotenoid derivatives even though references do not teach that the composition can be used for photoprotection of the skin. However, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the cited compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and

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103, expressed as a 102/103 rejection" (MPEP 2112). In this regard, it is noteworthy that the claims are directed to a composition comprising "10⁻¹²% to 20% by weight of a carotenoid or an unidentified "carotenoid derivative". There is nothing on the record to indicate to what extent a composition comprising carotenoids or unidentified carotenoid derivatives at the lower end of the range recited will have the required effect.

As noted *supra* the addition of yeast extract to probiotic lactic acid compositions is well known in the art for its viability enhancement.

Applicant's argue that the presently claimed oral composition includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced effect or response in respect of the photoprotection of the skin citing the Specification, page 14, lines 6-11. Yet the claims are directed to any lactic acid bacterial probiotic, with unidentified carotenoid derivatives or unidentified carotenoids added in a range that includes minuscule amounts.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

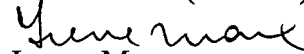
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651